

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS & AMENDMENTS

Claims 1-5 were pending in this application when last examined and stand rejected.

Claim 1 has been amended to clarify that the human gene over-expressing animal is a non-human animal selected from the group consisting of mouse, rat and rabbit. Support can be found at page 5, line 28 to page 6, line 5. Claim 1 has also been amended to better conform with US practice for claiming transgenic animals by reciting “which comprises” and instead of “carrying.”

Claims 1 and 3-5 have been amended to clarify that the human gene over-expressing animal is a transgenic animal as supported by the disclosure at page 6, line 26 and in original claim 1.

Claim 2 has been canceled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any canceled subject matter.

Claims 1 and 3-5 are pending upon entry of this amendment.

Claims 3-5 have been amended to remove dependency to cancelled claim 2.

Therefore, no new matter has been added by this amendment.

II. FOREIGN PRIORITY

Kindly acknowledge the foreign priority claim under 35 U.S.C. § 119(a)-(d) or (f), as well as receipt of the certified copies of the foreign priority document.

III. ENABLEMENT REJECTION

On pages 2-7 of the Office Action, claims 1-5 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification is enabling for a transgenic mouse whose genome

comprises a human hematopoietic prostaglandin D2 (PGD2) synthase gene, wherein said mouse expresses PGD2 in the lung, spleen and liver at a level more than five times that of the endogenous PGD2 of the transgenic mouse (*i.e.*, corresponds to Example 1 on pages 8-9), but not for any other transgenic animal.

This rejection is respectfully traversed as applied to the amended claims.

The test of enablement is whether one reasonably skilled in the art could make or use the invention based on the disclosure in the specification coupled with the knowledge in the art without undue experimentation.

The Office takes the position that only a mouse could be genetically modified at the time of filing of this application and that the disclosure only exemplifies a transgenic mouse whose genome comprises a human hematopoietic prostaglandin D2 (PGD2) synthase gene wherein said mouse expresses PGD2 in the lung, spleen and liver at a level more than five times that of the endogenous PGD2 of the transgenic mouse (*i.e.*, corresponds to Example 1 on pages 8-9).

It is again respectfully submitted that this characterization on the state of the art and the specification disclosure is incorrect. The specification at page 5, line 28 to page 6, line 5, describes a process for producing the claimed human gene over-expressing transgenic animal using standard techniques as disclosed in Gordon et al. (PNAS, vol. 77, no. 12, pp. 7380-7384 (1980)). In particular, the specification, at page 6, line 5, indicates that this technique may be applied to produce transgenic “animals of any and every species”.

Furthermore, as argued in the prior response, at the time of filing, there were many reports for making transgenic animals, other than mice. The prior response cited the following references as evidenced that transgenic animals other than mice were obtainable:

1. Hammer et al., “Production of transgenic rabbits; sheep and pigs by micro-injection, Nature, 315(6021):680-683 (1985);
2. Knight et al., “Transgenic rabbits with lymphocytic leukemia induced by the c-myc oncogene fused with the immunoglobulin heavy chain enhancer,” PNAS USA, 85:3130-3134 (1988);

3. Vise et al., "Introduction of a porcine growth hormone fusion gene into transgenic pigs promotes growth," J. Cell. Sci., 90 (Pt 2):295-300 (1988); and
4. Mullins et al., "Fulminant hypertension in transgenic rats harbouring the mouse Ren-2 gene," Nature, 344(6266):541-544 (1990).

Based on these references, transgenic animals, such as transgenic mice, transgenic rats and transgenic rabbits were known in the art at the time of filing of the instant application. It is respectfully submitted that one skilled in the art would be able to produce without undue experimentation a hematopoietic PGD2 synthase gene transgenic rat and rabbit in view of the guidance in the disclosure and the knowledge in the art. See for example, the Hammer reference, which describes production of transgenic rabbits, sheep and pigs by micro-injection. The Knight reference also discloses transgenic rabbits with lymphocytic leukemia induced by the c-myc oncogene fused with the immunoglobulin heavy chain enhancer. The Mullins reference discloses fulminant hypertension in transgenic rats comprising the mouse Ren-2 gene.

Thus, at the time of the filing, transgenic animals other than mice had been produced. As such, the skilled artisan upon reading the disclosure and given the knowledge in the art, could make and use the full breadth of the claims without undue experimentation.

In view of the above, the rejection of claims 1-5 under 35 U.S.C. § 112, first paragraph, is untenable and should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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